**Chapter 6. 510(k) Summary**

JUL 30 2012

# 510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

**1. Submitter Information**

**Establishment Registration Name and address:**

Sponsor Name: Leto Enterprises Incorporation

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**2. Application Correspondent Information:**

MEDLAB (Shenzhen) Information Service Co., Ltd.

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**3. Subject Device Information**

| | |
|---|---|
| Type of 510(k) submission: | Traditional |
| Device Common Name: | Facial Toning device |
| Trade Name: | Ageless Wonder Facial Toning Device |
| Classification Name: | Transcutaneous Electrical Nerve Stimulator |
| Review Panel: | Neurology |
| Product Code: | NFO |
| Regulation Class: | II |
| Regulation Number: | 882.5890 |

**4. Predicate Device Information**

| | |
|---|---|
| Sponsor: | Carol Cole Company |
| Device: | NuFace Facial Toning Device |
| 510(k) Number: | K072260 |

**5. Device Description**

The Ageless Wonder Facial Toning Device is a battery-powered portable EMS device. It applied specially designed bi-polar low voltage micro-current impulses on the face.

Not for use on injured or otherwise impaired skin or muscles, or use in any therapy or for the treatment, diagnosis, prevention or cure of any medical conditions or diseases. The device must only be used for the purpose stated – namely for the stimulation of facial muscles as indicated in the instruction manual for personal beauty purposes. All other uses shall be deemed improper

**6. Intended Use**

Ageless Wonder Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. The anatomical site for application of the Ageless Wonder Facial Toning Device is the face.

**7. Test Summary**

Ageless Wonder Facial Toning Device conforms to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2007
- IEC 60601-2-10, Medical electrical equipment - Part 2-10: Particular requirements for nerve and muscle stimulators,1987; A1,2001
- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.2009
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 2010

## 8. Comparison to Predicate Device

Compare with predicate device, they are very similar in design principle, intended use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Product Name | Ageless Wonder Facial Toning Device | Nuface | -- |
| K Number | Applying | K072260 | -- |
| Product Code | NFO | NFO | SE |
| Regulation Number | 21 CFR 882.5890 | 21 CFR 882.5890 | SE |
| **Intended Use and Indications for Use** | | | |
| Intended Use and Indications for Use | Ageless Wonder Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic use. The anatomical site for application of the Ageless Wonder Facial Toning Device is the face. | The NuFace Facial Toning Device is intended for facial stimulation and is indicated for over-the-counter cosmetic us. The anatomical site for application of the NuFace is the face. | SE |
| **SPECIFICATION** | | | |
| Patient Protection | Type BF | Type BF | SE |
| Type of Protection against Electric Shock | Internally powered equipment | Internally powered equipment | SE |
| Battery life | Approximately 2 hours to 3 hours at nominal settings | Approximately 2 hours to 3 hours at nominal settings | SE |
| Channel | Single Channel | Single Channel | SE |
| Current | From 0 to 43.2 uA (From 0 to 1000 Ohm) | From 0 to 400 uA | Note 1 |
| Pulse Width Range | 150 us | 112 ms | Note 1 |
| Display | LCD | LED | Note 2 |
| **DIMENSIONS/WEIGHT** | | | |
| Dimensions | 98.5mm x 53mm x 27.5mm | 7cm(L)x 2.5cm(W) x 1cm(D) | Note 3 |
| Device Net Weight | 90g (including headset) | 1.8 lbs | |
| **OPERATING & STORAGE CONDITIONS** | | | |
| Storage Environment | Temperature: 10℃ ~ 55℃<br>Relative Humidity: ≤95%<br>Atmospheric Pressure: 500hPa ~ 1060 hPa | None | Note 3 |

| Elements of Comparison | Subject Device | Predicate Device | Verdict |
|---|---|---|---|
| Working Environment | Temperature: 5℃ ~ 40℃<br>Relative Humidity: ≤80% RH<br>Atmospheric Pressure: -70 kPa ~ 106 kPa | None | Note3 |
| **Evaluation** | | | |
| Electrical, Mechanical and Thermal Evaluation | IEC 60601-1<br>IEC 60601-1-2 | IEC 60601-1 | Note 1 |
| Biocompatibility Evaluation | All the accessories are cleared or listing by FDA, which are evaluated by the biocompatibility standard ISO 10993 -5, -10. | The biocompatibility of the accessories is evaluated as per the requirement of the standard ISO 10993 -5, -10. | SE |
| **Recommendation Accessory** | | | |
| Heavy Duty Battery | 1.5V AAA x 2 pieces | 9-volt battery | Note 1 |
| Cable | 0.3mm | Carol Cole Derma-Gel NuFace Conductivity Gel (8.45 fl oz / 250 ml) | Note 4 |
| Conductive Sponge | Thickness - 0.5mm | Carol Cole Optimizing Mist (8 fl oz / 237 ml) | Note 4 |

**Note 1:**

Both subject device and predicate device are complied with IEC 60601-1. The difference of their rating does not affect the safety and effectiveness.

**Note 2:**

The display of the subject device is LCD, while the display of predicate device is LED. But they are complied with IEC 60601-1, and they can display required information of the device.

**Note 3:**

Although some specifications of performance specification, dimensions/weight, operating & storage conditions are different for subject device and predicate device, they are both complied with IEC 60601-1.

**Note 4:**

Although some specifications for recommendation accessories of subject device and predicate device are different, they are all FDA Listing or cleared devices. The differences do not affect the safety and effectiveness.

**9. Conclusion**

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate devices.

**10. Summary Prepared Date**

**July 11th, 2012**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Leto Enterprises Incorporation
% Ms. Sabrina Wei
Manager
MEDLAB (Shenzhen) Information Service Co., Ltd.
Room 2706, Block A, Jinyuan Building
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Shenzhen, Guangdong 518034
China

Re: K120511
Trade/Device Name: Ageless Wonder Facial Muscle Stimulation System
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: II
Product Codes: NFO
Received: July 20, 2012

Dear Ms. Wei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**Chapter 5. Statement of Indications for Use**

# Indications for Use

510(k) Number (if known): Applying

Device Name: Ageless Wonder Facial Muscle Stimulation System

Indications for Use:
Ageless Wonder Facial Muscle Stimulation System is intended for facial stimulation and is indicated for over-the-counter cosmetic use.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number k120511

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number k120511